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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,615	12/30/2003	Arnold P. Nerenberg	NERE-3815	7492

5409 7590 12/19/2006

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EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,615	NERENBERG, ARNOLD P.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed August 11, 2006 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1, 21, and 32 have been amended.

Remarks drawn to rejections of Office Action mailed May 18, 2006 include:

112 1st paragraph rejections: which have been maintained for reasons of record.

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

An action on the merits of claims 1-57 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The rejection of claims 1-57 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. Applicants are not enabled for the combinations as instantly claimed.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in ***In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)***. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:
(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims - The nature of the invention

Claim 1 is drawn to a nutritional supplement comprising L-arginine-2-pyrrolidone-5-carboxylate, L-lysine hydrochloride, and a cortisol suppressant. Claims 2-4 limit the cortisol suppressant. Claims 5-14 add additional agents to the composition, such as L-leucine (claim 5), bee pollen (claim 6), L-tyrosine (claim 7), etc. Claim 15 provides the composition does not include a steroid or hormone. Claims 16-20 provide the form of the supplement, i.e. powder, tablets, wafers, liquid, or capsule form. Claim 21 is drawn to a nutritional supplement consisting essentially of L-arginine-2-pyrrolidone-5-carboxylate, L-lysine hydrochloride, and a cortisol suppressant. Claims 22-26 limit the composition and the cortisol suppressant. Claims 27-31 limit the form of the supplement. Claim 32 is drawn to a nutritional supplement consisting essentially

of L-arginine-2-pyrrolidone-5-carboxylate, L-lysine hydrochloride, a cortisol suppressant, and an additional agent. Claims 31-52 limit the additional agent. Claims 53-57 limit the form of the supplement.

The state of the prior art

L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride are known to provide a synergistic effect in increasing the release of pituitary somatotrophin (HGH) and insulin, as seen by Isidori et al. (see applicants IDS). Acetyl-L-carnitine is known to be capable of restoring the integrity of the cardiac mitochondrial membrane altered by aging, thereby restoring the normal activity of cytochrome oxidase which allows for a more efficient oxidative phosphorylation and therefore improves cardiac performance in aged animals, as seen by US 5,977,162. Maltodextrin is known in the art to be a sweetener. Combination therapy, and drug-drug interactions are known in the art to have various effects, and when physicians use several drugs in combination, they face the problem of knowing whether a specific combination in a given patient has the potential to result in an interaction, and if so, how to take advantage of the interaction if it leads to improvement in therapy or how to avoid the consequences on an interaction if they are adverse. A potential drug interaction refers to the possibility that one drug may alter the intensity of the pharmacological effects of another drug if given concurrently. The net result may be enhanced or diminished effects of one or both of the drugs, or the appearance of new effects which is not seen with either drug alone. The frequency of significant beneficial or adverse effects is unknown. The interaction between the drugs may be pharmacokinetic, i.e. alteration of the absorption, distribution, or elimination of one drug by another, or may be pharmadynamic, i.e. interactions between agonists and antagonists at drug receptors. The most

important drug-drug interactions occur with drugs that have serious toxicity and low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences. Additionally, drug-drug interactions can be clinically important if the disease being controlled with the drug is serious or potentially fatal if left under treated. Drugs are known to interact at any point during their absorption, distribution, metabolism, or excretion; the result being an increase or decrease in concentration of the drug at the site of action. As individuals vary in their rates of disposition of an given drug, the magnitude of an interaction that alters pharmacokinetic parameters is not always predictable, but can be very significant. See Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 10th Edition, McGraw-Hill Medical Publishing Division, 2001, pages 54-56.

The level of predictability in the art

As seen by Goodman & Gilman, the art of combination therapy is unpredictable. Drug-drug interactions are known to be beneficial or adverse, yet there is no way to know until the drugs are actually tested in combination with each other. Especially in view of the fact that Isidori et al. show that the combination of L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride increase plasma HGH levels from about 10-15 ng/ml when using either of the drugs individually to about 90 ng/ml when using a combination, after 90 minutes. This highly synergistic effect shows that the combination of two agents produced unexpected results.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to use the claimed method commensurate in the scope with the instant claims. There is a lack of data and examples

which adequately represent the claims as written. Applicants have not provided any indication of what drugs might be toxic and what the drugs therapeutic indexes are. Applicants have merely listed various drugs in the specification.

The existence of working examples

There are no working examples in the instant application. There are no formulations made, and nothing tested in any capacity on any subjects. Applicants state that "each ingredient of the nutritional supplement of the present invention may be prepared in accordance with any method known to one of ordinary skill in the art. Alternatively, each ingredient may be obtained in a fully prepared from a commercially available source" (see page 10 of specification). Applicants also state that "the dissolvable form may be prepared by any method known to one of ordinary skill in the art", and that "the liquid form may be prepared by any method known to one of ordinary skill in the art".

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable one to make or use the combination of the claimed agents without undue experimentation. It is noted that the specification should teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. See ***In re Gardner, 166 USPQ 138 (CCPA 1970).***

Applicant's arguments filed August 11, 2006 have been fully considered but they are not persuasive. Applicants argue that they have taught how to make and use the invention in the

specification. Applicants argue that the specification teaches how to obtain the ingredients and the structural forms into which the ingredients are assembled. Applicants also state that they teach how to use the invention as a nutritional supplement. Applicants also state that the specification must be taken as complying unless there is reason to doubt the object truth contained therein, and that the examiner needs to state why there is doubt regarding the same. Applicant also argues that the examiner's basis for alleging undue experimentation is based on the fact that the specification does not contain various items, however there is no legal precedence for these items being required. In response the examiner would like to note that it is still believed that one skilled in the art would be required to practice undue experimentation to use the instant invention. The combination of 2 of the 3 ingredients used in applicants independent claim 1 produced completely unexpected results, as evidenced by Isidori et al. Due to the fact that this combination produced unexpected results, adding additional agents would also be expected to produce unexpected results. Applicants have listed various agents in their specification, and various dosage forms for administration, but does not actually test anything to see if indeed the compositions indeed were effective in nutritional supplementation, or if they possibly produced results which would have not been expected, as was done with the combination of the arginine and lysine compounds. Moreover, Goodman & Gilman discuss the importance of drug-drug interactions, and the possibly events which may occur in these interactions. Making and testing all of the various claimed combinations of agents to determine if they also produced various unexpected results, as was done with the synergism produced by the combination of the arginine and lysine compounds in Isidori et al., would be seen to be undue experimentation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
December 10, 2006

Shaojia A. Jiang
Art Unit 1623
Supervisory Patent Examiner